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May 20, 2009

NIH Stem Cell Guidelines MSC 7997 9000 Rockville Pike Bethesda, Maryland 20892-7997

Re: Request for Public Comment on NIH Guidelines for Human Stem Cell Research

To Whom It May Concern:

On behalf of the American Association for the Advancement of Science (AAAS), thank you for the opportunity to comment on the National Institutes of Health (NIH) Guidelines for Human Stem Cell Research, published in the *Federal Register* on April 23.

We are pleased to see NIH move quickly to issue guidelines that will enable scientists to move forward in this crucial field. Though some scientists may have hoped for more, we believe that federal funding of the type of research the guidelines describe—on stem cells derived from donated, excess human embryos from fertility treatments—will provide an opportunity to achieve important progress. AAAS has long maintained the need for strong ethical guidelines underlying federal funding in this area, dating back to our 1999 report, Stem Cell Research and Applications, which is in line with many of the principles laid out in the NIH release.

That said, we believe there are matters that NIH should consider before finalizing these guidelines. One issue is funding for research involving current embryonic stem cell lines, including those that were eligible for federal funds per the previous Administration's 2001 policy. Since informed consent standards have changed, it is unclear how many of the lines used in ongoing studies would be in compliance with the new guidelines. We believe strongly that stringent informed consent procedures are a necessary ethical safeguard for this kind of research. Yet there needs to be a way to "grandfather in" stem cell lines that have followed the core principles underlying the proposed guidelines, such as voluntary informed consent with no undue inducements offered to donors. Reconsent may be an impractical burden on researchers, leading some to forgo promising research. An ethically sound solution would be to accept stem cell lines that adhered to strict ethical provisions in force at the time of their derivation. We encourage NIH to study this matter and possible solutions very closely. In addition, we urge NIH to maintain a stem cell registry to inform scientists of eligible lines.

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While AAAS supports NIH in taking this important yet pragmatic step toward advancing stem cell research, many universities and research facilities continue to face the difficulty of how to administer research programs funded by the federal government versus the private sector. These institutions must still confront the fact that restrictions on federal support of embryonic stem cell research limit the ability of researchers to share equipment and laboratory space, and that the need for separate facilities inevitably drives up costs. Thus, we encourage NIH to explore administrative, legal and ethical solutions to the problems inherent in the separation of public and private research.

AAAS is the world's largest multidisciplinary science society, representing the interests of ten million scientists worldwide, and publisher of the prestigious peer-reviewed journal *Science*. We have a longstanding interest and expertise in stem cell research and bioethics; our reports, statements, letters and congressional testimony are available on our website. We stand ready to work with you in addressing this important and complex subject.

Sincerely,

Alan I. Leshner

http://www.aaas.org/spp/sfrl/projects/stem/report.pdf

² http://www.aaas.org/spp/cstc/briefs/stemcells/stemaaas.shtml